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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,880	05/14/2001	Gregory J. Riggins	00250.00003	6566

22907 7590 07/11/2005

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WASHINGTON, DC 20001

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT PAPER NUMBER

1643

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/853,880

**Applicant(s)**

RIGGINS ET AL.

**Examiner**

Christopher H. Yaen

**Art Unit**

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13, 16 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13, 16 and 18-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

**Re: Riggins *et al***

1. The amendment filed 3/17/2005 is acknowledged and entered into the record. Accordingly, claims 1-12,14-15,17, and 23-47 are canceled without prejudice or disclaimer.
2. Claims 13,16, and 18-22 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections Maintained - 35 USC § 112, 1<sup>st</sup> paragraph***

4. The rejection of claims 13, 16, and 18-22 under 35 USC § 112, 1<sup>st</sup> paragraph as lacking an enabling disclosure is maintained for the reasons of record. Applicant argues that the instantly filed specification is enabling. To support this assertion, applicant submits a manuscript by Kuan *et al* that demonstrates that GPNMB is expressed as a protein and that the up-regulation of the mRNA is correlative to the protein expression. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Publications dated after the filing date providing information publicly first disclosed after the filing date generally cannot be used to show what was known at the time of filing. *In re Gunn*, 537 F.2d 1123, 1128, 190 USPQ 402,405-06 (CCPA 1976); *In re Budnick*, 537 F.2d 535, 538, 190 USPQ 422, 424 (CCPA 1976). While a later dated publication cannot supplement an insufficient disclosure in a prior dated application to

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make it enabling, applicant can offer the testimony of an expert based on the publication as evidence of the level of skill in the art at the time the application was filed. *Gould v. Quigg*, 822 F.2d 1074, 1077, 3 USPQ2d 1302, 1304 (Fed. Cir. 1987). In the instant case, applicant's application provided little information regarding the protein expression profile of the GPNMB protein. Therefore, at the time the invention was filed, applicant was not aware of such correlation between the protein expression levels and its correlation to mRNA expression levels. Moreover, the manuscript provided is not fully commensurate in scope to the claimed invention because the claims are drawn to a method of delivering a reagent to a glioblastoma, wherein one of the preferred embodiments is the delivery of the antibody to a human. The specification nor the manuscript provide enabling disclosure regarding the delivery of an antibody to a GPNMB protein to a cell in a human as claimed.

Applicant further argues that the cited references provided in the office action are "out of date and do not reflect the current widespread use of antibody therapeutics". Specifically, applicant argues that Curti *et al* discusses "potential impediments" and offers suggestions to improve drug delivery. Further, applicant also contends that Jain's statements are out of date and was followed by the approval of many antibodies for the treatment of cancer. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

The cited references serve the point of providing a general statement regarding the overall unpredictability in the field of immunotherapeutics. The instantly filed applicant offers one of skill in the art little information regarding the nature and effects of

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an antibody for the purposes of targeting an antigen, which at the time of filing was not particularly well characterized. Thus, in the absence of objective evidence to the contrary, one of skill in the art would be forced into undue experimentation given the generally unpredictable nature of immunotherapeutics as outlined by both Curti *et al* and Jain and the given limited disclosure regarding the nature and or expression patterns associated with the GPNMB protein of the instantly claimed invention.

Therefore the rejection under 35 USC § 112, 1<sup>st</sup> paragraph as lacking enablement is maintained for the reasons of record.

### ***Conclusion***

**No claim is allowed.**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

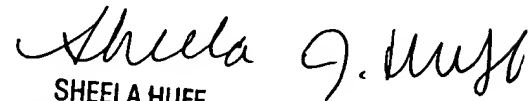
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen  
Art Unit 1643  
July 5, 2005

  
SHEELA HUFF  
PRIMARY EXAMINER